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CLINICAL RESEARCH | Interventional Cardiology

Characteristics and Long-Term Outcomes of Percutaneous Revascularization of Unprotected Left Main Coronary Artery Stenosis in the United States

A Report From the National Cardiovascular Data Registry, 2004 to 2008

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Objectives This study sought to assess percutaneous coronary intervention (PCI) for unprotected left main coronary artery (ULMCA) stenosis in routine U.S. clinical practice.

Background Percutaneous coronary intervention for ULMCA stenosis is controversial; however, current use and outcomes of ULMCA PCI in routine U.S. clinical practice have not been described.

Methods We evaluated 5,627 patients undergoing ULMCA PCI at 693 centers within the National Cardiovascular Data Registry Catheterization Percutaneous Coronary Intervention Registry for temporal trends in PCI use (2004 to 2008), patient characteristics, and in-hospital mortality. Thirty-month mortality and composite major adverse events (death, myocardial infarction, and revascularization) with drug-eluting versus bare-metal stents were compared using inverse probability weighted (IPW) hazard ratios (HRs) in a nonrandomized Medicare-linked (age ≥65 years) patient cohort (n = 2,765).

Results ULMCA PCI was performed in 4.3% of patients with ULMCA stenosis. Unadjusted in-hospital mortality rates ranged from 2.9% for elective cases to 45.1% for emergent/salvage cases. By 30 months, 57.9% of the elderly ULMCA PCI population experienced death, myocardial infarction, or revascularization, and 42.7% died. Patients receiving drug-eluting stents (versus bare-metal stents) had a lower 30-month mortality (IPW HR: 0.84, 95% confidence interval [CI]: 0.73 to 0.96), but the composite of major adverse events were similar (IPW HR: 0.95, 95% CI: 0.84 to 1.06).

Conclusions In the United States, ULMCA PCI is performed in <5% of patients with ULMCA disease and is generally reserved for those at high procedural risk. Adverse events are common in elderly patients and are related to patient and procedural characteristics, including stent type. (J Am Coll Cardiol 2012;59:648–54) © 2012 by the American College of Cardiology Foundation

In the United States, revascularization of unprotected left main coronary artery (ULMCA) stenosis has traditionally been achieved with cardiac surgery. However, American College of Cardiology/American Heart Association coronary revascularization guidelines have upgraded ULMCA percutaneous coronary intervention (PCI) in coronary artery

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bypass grafting–eligible patients from a class III (i.e., "should not be performed") to a Class IIb recommendation (i.e., "may be considered") (1) based on recent evidence (2).

Against this background, we examined trends in ULMCA PCI and long-term clinical outcomes in U.S. practice using a Medicare-linked cohort from the NCDR (National Cardiovascular Data Registry) CathPCI (Catheterization Percutaneous Coronary Intervention) registry.

Methods

Study population. Analyses included all patients without a prior history of coronary artery bypass graft surgery but with a significant ULMCA stenosis at any of the 693 centers with CathPCI registry participation between January 1, 2004, and December 31, 2008 (Fig. 1). A subgroup of elderly patients with linkage to Medicare inpatient claims was identified for longitudinal follow-up.

Follow-up information. To enable 30-month follow-up, registry files were linked to Medicare 100% inpatient fee-for-service claims, as previously described (3,4). The Duke University School of Medicine Institutional Review Board granted a waiver of informed consent and authorization for this study.

Clinical endpoints. Primary endpoints included death and a composite of major adverse events (i.e., death, myocardial infarction, and repeat revascularization) and were assessed using Medicare inpatient claims, as previously described (3).

Statistical analysis. Baseline patient and procedural characteristics were summarized as counts and percentages for categorical variables and mean with standard deviations for continuous variables. The association of the ULMCA PCI rate with the year of index hospitalization was evaluated using a chi-square test of trend. Statistical significance was defined as a p value ≤0.05. SAS statistical software (version 9.1, SAS Institute, Cary, North Carolina) was used for all calculations.

Propensity scores (including 107 covariates) (3) were used to balance drug-eluting stents (DES) versus bare-metal stents (BMS) treatment groups (5), and inverse probability weighted estimators incorporating the propensity scores were used to balance treatment groups (6).

Abbreviations and Acronyms

- **BMS** = bare-metal stent(s)
- **CI** = confidence interval
- **DES** = drug-eluting stent(s)
- **HR** = hazard ratio
- **PCI** = percutaneous coronary intervention
- **ULMCA** = unprotected left main coronary artery

For each of the primary endpoints and within each of the prespecified subgroups, cumulative incidence rates at 1, 12, and 30 months were calculated using inverse probability weighted estimators (7), and adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated based on sandwich-estimated standard errors (8).

Subgroup analyses. High-urgency revascularization procedures included primary PCI, rescue or facilitated PCI for ST-segment elevation myocardial infarction, or those involving pre-procedural cardiogenic shock, or emergent or salvage status. Logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) values were calculated using the variable mapping algorithm in Online Table 1 and classified as high (≥33.5%) or low (<33.5%) based on prior literature (9).

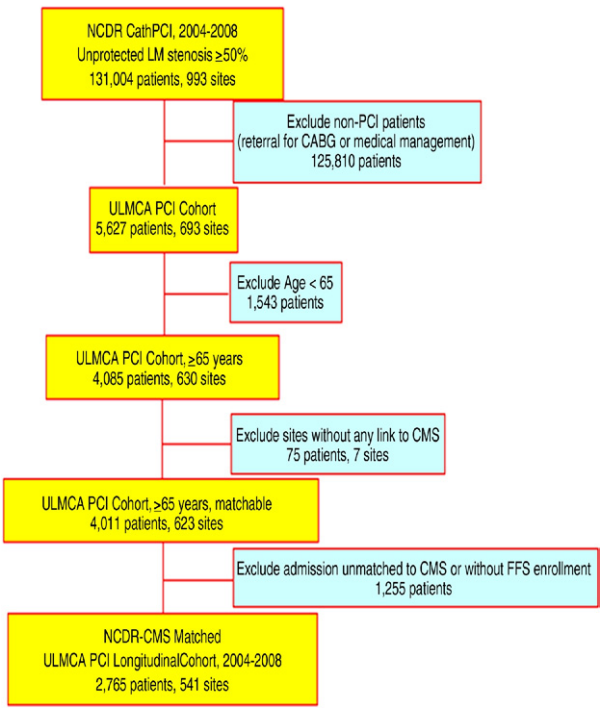

Figure 1 Population Flow Diagram

We began with a study population of 131,004 patients from 993 sites and, after exclusions, ended with a final study population of 2,765 patients from 541 sites. CABG = coronary artery bypass graft; CathPCI = Catheterization Percutaneous Coronary Intervention registry; CMS = Centers for Medicare & Medicaid Services; FFS = fee for service; NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention; ULMCA = unprotected left main coronary artery.

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Table 1 Population Characteristics of All NCDR CathPCI Registry Patients With ULMCA Stenosis

	Stented (n = 5,627)	Not Stented* (n = 125,377)	p Value
Patient characteristics			
Age, yrs	72.0 ± 12.3	68.5 ± 11.2	<0.001
Male	3,349 (59.5%)	87,678 (69.9%)	<0.001
Logistic EuroSCORE (high)†	752 (13.4%)	4,783 (3.8%)	
Race/ethnicity			
Caucasian	4,723 (84.0%)	104,344 (85.0%)	0.062
African American	264 (4.7%)	6,537 (5.3%)	0.041
Asian	127 (2.3%)	2,005 (1.6%)	<0.001
Hispanic	198 (3.5%)	3,970 (3.2%)	0.229
Current smoking	1,003 (17.8%)	26,514 (23.5%)	<0.001
CHF	4,563 (81.1%)	77,921 (69.0%)	<0.001
HTN	4,488 (79.8%)	86,967 (77.1%)	<0.001
Renal failure			
No dialysis	481 (8.6%)	6,592 (5.3%)	<0.001
Dialysis	251 (4.5%)	2,743 (2.2%)	<0.001
Diabetes			
Noninsulin-requiring	1,249 (22.2%)	26,503 (23.5%)	0.024
Insulin	755 (13.4%)	11,993 (10.6%)	<0.001
Peripheral vascular disease	1,280 (22.8%)	19,188 (17.1%)	<0.001
Stroke	1,160 (20.6%)	17,244 (15.3%)	<0.001
Chronic lung disease	1,532 (27.2%)	21,705 (19.3%)	<0.001
Prior PCI	1,707 (30.3%)	21,433 (17.1%)	<0.001
Prior MI	1,852 (32.9%)	22,549 (20.1%)	<0.001
Indication			
Stable angina	797 (14.2%)	18,808 (15.0%)	0.084
UA	1,568 (27.9%)	37,273 (29.7%)	0.003
NSTEMI	1,396 (24.8%)	23,500 (18.7%)	<0.001
STEMI	752 (13.4%)	11,727 (9.4%)	<0.001
Pre-procedural shock	871 (15.5%)	4,306 (3.9%)	<0.001
Pre-procedural IABP	360 (6.4%)	300 (0.3%)	<0.001
Bifurcation lesion	1,812 (32.2%)	289 (0.23%)	<0.0001
Hospital region			
Northeast	908 (16.1%)	17,809 (14.2%)	<0.001
South	1,618 (28.8%)	45,227 (36.2%)	<0.001
Midwest	1,975 (35.1%)	40,790 (32.6%)	<0.001
West	1,122 (20.0%)	21,228 (17.0%)	<0.001
Hospital setting			
Rural	465 (8.3%)	18,790 (15.0%)	<0.001
Suburban	1,211 (21.5%)	34,039 (27.1%)	<0.001
Urban	3,951 (70.2%)	72,548 (57.9%)	<0.001

Values are mean ± SD or n (%). *Patients "Not Stented" include those referred to coronary artery bypass graft surgery and medically managed. †High logistic EuroSCORE defined as >33.5%.

CathPCI = Catheterization Percutaneous Coronary Intervention registry; CHF = congestive heart failure; EuroSCORE = European System for Cardiac Operative Risk Evaluation; HTN = hypertension; IABP = intra-aortic balloon pump; MI = myocardial infarction; NCDR = National Cardiovascular Data Registry; NSTEMI = non–ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina; ULMCA = unprotected left main coronary artery.

Intravascular ultrasound use was specific to the left main lesion, but its timing (i.e., pre-PCI, post-PCI, or both) was unspecified.

Sensitivity analyses. A post hoc "cause of death" analysis was performed among patients surviving to hospital discharge. Additionally, 2 sensitivity analyses were performed to evaluate the potential influence of unmeasured confounders and treatment selection bias (Online Table 2).

Results

Study population. From January 2004 to December 2008, 131,004 patients having ≥50% ULMCA stenosis were included in the CathPCI registry (Fig. 1), with 4.3% receiving ULMCA PCI. Compared with patients not treated with PCI, stented patients were older with a higher prevalence of both chronic comorbidities and acute pre-procedural clinical instability (Table 1).

Of the 5,627 patients who underwent PCI for ULMCA stenosis, 4,085 (72.6%) were ≥65 years of age, including 2,765 (69%) with successful linkage to Medicare inpatient claims files (Fig. 1, Online Table 1). Medicare-linked patients were largely representative of the overall Medicare-eligible cohort.

Temporal trends of ULMCA PCI in the NCDR CathPCI registry. Use of ULMCA PCI was rare at most centers (660 centers with <30 total procedures ["low" volume, <6 procedures per year]; 25 centers with 30 to 75 total procedures ["moderate" volume, 6 to 15 procedures per year]; and 8 centers with >75 ULMCA procedures over 5 years ["high" volume, >15 procedures per year]). The proportion of patients with ULMCA disease treated with ULMCA PCI at centers participating in the CathPCI registry increased slightly throughout this interval (3.8% to 4.9%, $p < 0.0001$) (Fig. 2A), and most ULMCA PCI cases occurred in lower-urgency settings (Fig. 2B). DES were used in a majority (81.8%) of lower-urgency procedures; however, DES and BMS use was similar in high-urgency procedures after 2006.

Overall ULMCA NCDR CathPCI cohort: in-hospital outcomes. Overall, 95% of ULMCA patients survived to hospital discharge. Stented ULMCA patients had a higher unadjusted in-hospital mortality rate compared with non-stented patients (13.1% vs. 4.6%, $p < 0.0001$). In-hospital mortality was associated with clinical urgency, with a greater in-hospital mortality observed among patients with high (45.1%) versus low (2.9%) clinical urgency and high (26.0%) versus low (3.2%) pre-procedural logistic EuroSCORE.

Medicare-linked ULMCA PCI cohort: longitudinal outcomes. Of the 2,765 patients with longitudinal follow-up, 57.9% experienced a major adverse event by 30 months (death: 42.7%; myocardial infarction: 8.2%; repeat revascularization: 17.5%).

By 30 months, a similar unadjusted incidence of death was observed across low-, moderate-, and high-volume centers for both lower-urgency (35.4% vs. 36.4% vs. 33.9%, $p = 0.2$) and higher-urgency ULMCA PCI procedures (65.1% vs. 73.2% vs. 59.9%, $p = 0.1$). Composite events for high-urgency patients were most common among centers with the highest ULMCA PCI volume (low volume: 72.7%; moderate volume: 76.9%; high volume: 80.0%; $p = 0.7$)—a trend that reached significance among lower-urgency patients (50.1%, 52.5%, and 60.3%, respectively; $p = 0.0005$).

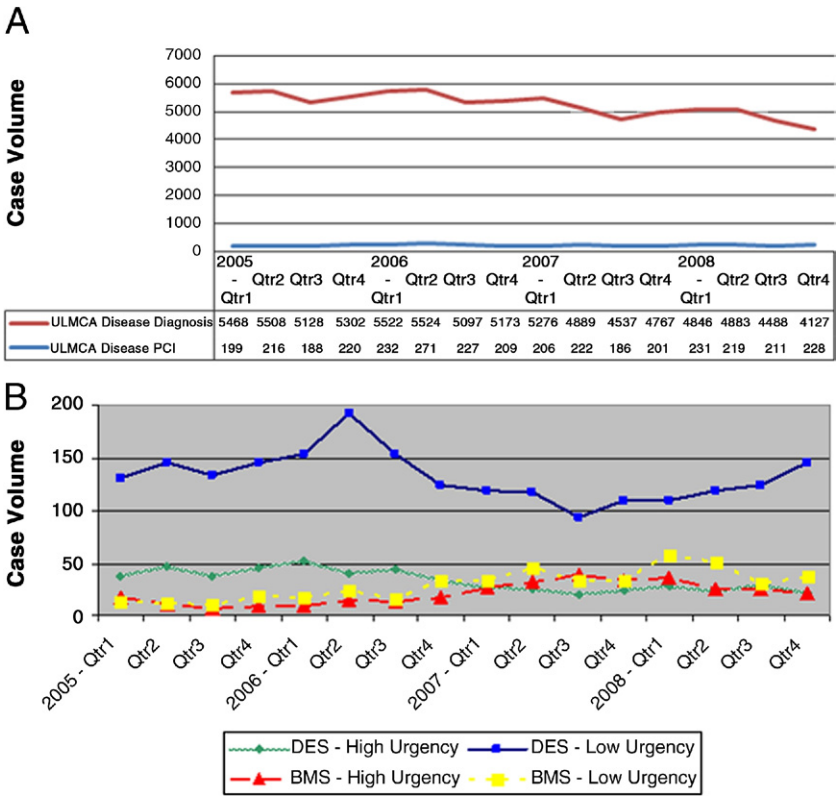

Figure 2 NCDR CathPCI ULMCA Case Volume

Displays **(A)** time-trend in the unprotected left main coronary artery (ULMCA) percutaneous coronary intervention (PCI) case volume as a percentage of overall ULMCA disease detection; and **(B)** changing profile of stent type for ULMCA PCI over time, stratified by procedural urgency. BMS = bare-metal stent(s); DES = drug-eluting stent(s); Qtr = quarter.

The 30-month outcomes stratified by clinical features are presented in Figure 3. Patients with the highest unadjusted incidence of major adverse events by 30 months included those with high logistic EuroSCORE values (76.6% vs. 53.9% for low logistic EuroSCORE values, $p < 0.001$), high clinical urgency (74.2% vs. 52.8% for low urgency, $p < 0.001$) (Fig. 4), and bifurcation lesions (64.8% vs. 54.7% for ostial or mid-body, $p < 0.001$) (Fig. 5).

The relative hazard of death by 30 months was lower among DES-treated versus BMS-treated patients both before and after adjustment by propensity weighting (39.6% vs. 52.7%; unadjusted HR: 0.60, 95% CI: 0.52 to 0.68; adjusted HR: 0.84, 95% CI: 0.73 to 0.96). However, no risk-adjusted difference in composite events was observed (adjusted HR: 0.95, 95% CI: 0.84 to 1.06) (Fig. 6). The relative risk of death and composite major adverse events associated with the use of DES versus BMS was consistent across most of the subgroups examined (Figs. 3A and 3B).

Discussion

This analysis represents the first national report of outcomes with ULMCA PCI in the United States and the largest reported experience of ULMCA PCI to date. It highlights 3 main findings. First, as of 2008, percutaneous treatment of ULMCA disease in the United States is uncommon and generally reserved for those with either a high burden of noncardiac disease or emergent clinical presentations. Second, elderly patients receiving ULMCA PCI are at high risk for major adverse events following the procedure, with 40% dying within the first 3 years of follow-up. Finally, the risk of adverse events appears related to certain procedural characteristics, including stent choice.

Temporal trends in ULMCA PCI. In the United States, the proportion of ULMCA patients treated with percutaneous revascularization remains low, but it is slowly increasing. Through 2008, most centers performed <1 ULMCA PCI per month, although an increase in the volume of lower-urgency procedures suggests increasing general acceptance of elective PCI for ULMCA at some centers. Consistent with international trends (10), DES remains the predominant stent platform for lower urgency procedures in the United States.

Outcomes following PCI for ULMCA stenosis. In the United States, ULMCA PCI is performed primarily in patients with a high burden of comorbidities and frequently in those with high-urgency clinical presentations. In this

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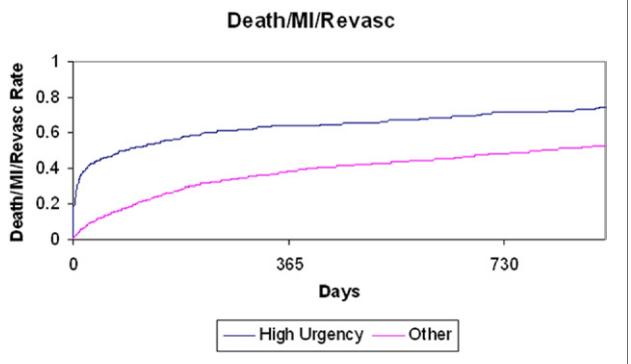

Figure 3 **Comparative Effectiveness of BMS Versus DES for Left Main Coronary Interventions in Select Patient Subgroups**

Displays **(A)** 30-month death (hazard ratio [HR] <1.0 favors drug-eluting stent [DES]); and **(B)** 30-month death, myocardial infarction (MI), or repeat revascularization (Revasc) (HR <1.0 favors DES). BMS = bare-metal stent(s).

population, in-hospital mortality was substantially higher in those with ULMCA disease who were treated percutaneously; however, this early risk is driven by those with high-urgency, rather than lower-urgency, presentations.

Among ULMCA patients selected for PCI in the United States, 30-month mortality is high (42.7%), with a predominance of cardiovascular events. These findings are especially notable when compared to the 10% mortality reported at 30 months in the MAIN-COMPARE (Korean Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) study (11), and the 4% mortality reported at 1 year in the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) trial (12). The increased patient age, burden of comorbidities, and clinical acuity of the NCDR ULMCA PCI cohort likely account for some portion of the difference in outcomes, and the outcomes reported here are more consistent with both early international reporting of ULMCA PCI outcomes in nonoperable patients (26.5% event-free survival at 9 months) (13) and those reported in octogenarians undergoing ULMCA PCI within the Canadian health system (56.7% event-free survival at 2 years) (14). These data highlight the need for continued surveillance of ULMCA PCI in the United States.

In addition to identifying several patient subgroups at increased risk of adverse outcomes (i.e., patients with bifurcation lesions), we have also identified important trends in procedural technique. For example, single-stent techniques, which have recently been associated with improved outcomes (15), were less common in this ULMCA PCI population (37.5%), but they were associated with improved long-term outcomes as compared with 2-stent techniques. Also, the use of intravascular ultrasound for procedural guidance was much less common (18%) than reported elsewhere (e.g., 78% in the MAIN-COMPARE registry) (16). In this cohort, intravascular ultrasound use was associated with a lower unadjusted incidence of both major adverse events (51% vs. 59%) and death (35% vs. 44%), adding to the growing body of nonrandomized literature supporting its use during ULMCA stenting (17).

Finally, our results are consistent with prior reports suggesting that DES are superior to BMS for the treatment of left main lesions (18). Here, DES were associated with improved survival when compared with BMS, but the mechanism by which stent type affects the risk of death in this population remains unclear.

Study limitations. These data represent the largest-ever experience with percutaneous revascularization of ULMCA disease, and the first-ever report of the U.S. national experience with these procedures; however, several limitations are notable. First, the reporting of diagnostic-only procedures is voluntary in most health systems and is believed to be less reliable at some centers. Second, the NCDR data does not allow a direct comparison of outcomes with percutaneous, surgical, and medical treatment strategies. Third, the longitudinal cohort is drawn from a Medicare FFS subgroup of the overall population in the United States; however, this cohort is highly representative of elderly patients undergoing percutaneous ULMCA revascularization in the United States. Fourth, outcomes are assessed using inpatient claims data and, therefore, are subject to inherent reporting errors and detection biases. For example, the exclusion of outpatient "observational" hospital visits potentially resulted in an underestimation of the incidence of repeat revascularization. Fifth, although 66% of the deaths with an attributable "cause" occurred in-hospital, the use of Medicare claims to ascertain the true "cause of death" is imprecise and should be viewed simply as hypothesis generating. Finally, the outcome comparison for patients treated with DES versus BMS is subject to unmeasured biases inherent to the device selection, which may favor DES (3). A comparison to clinical trial data is not

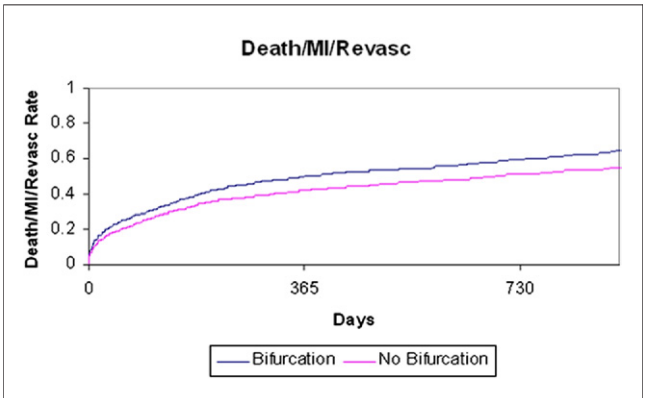

Figure 4 **Unadjusted Cumulative Incidence by Procedural Urgency**

Unadjusted cumulative incidence of death, MI, or repeat Revasc, stratified by procedural urgency. Abbreviations as in Figure 3.

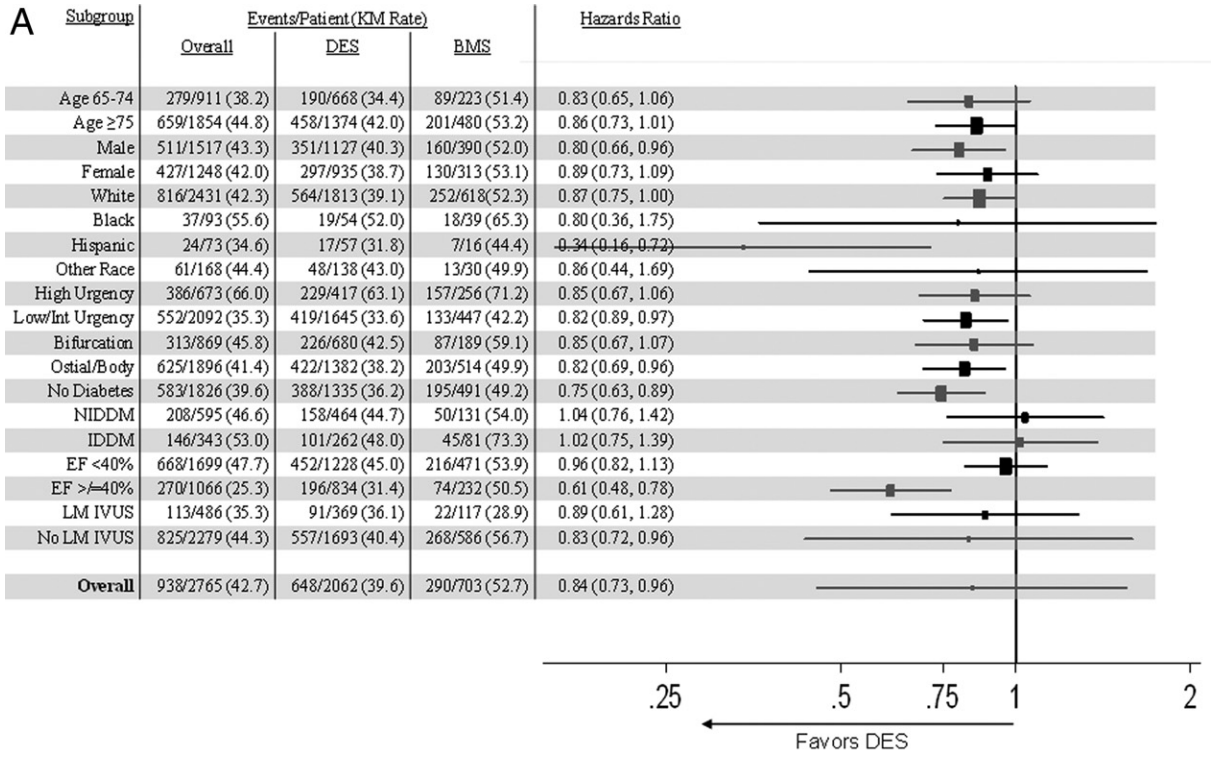

Figure 5 **Unadjusted Cumulative Incidence by Lesion Location**

Unadjusted cumulative incidence of death, MI, or repeat Revasc, stratified by left main lesion location. Note: The high incidence of death/MI/revascularization at the beginning of follow-up (t = 0) reflects a high incidence of in-hospital adverse events among high-urgency patients. EF = ejection fraction; IDDM = insulin-dependent diabetes mellitus; IVUS = intravascular ultrasound; KM = Kaplan-Meier; LM = left main; NIDDM = noninsulin-dependent diabetes mellitus; other abbreviations as in Figure 3.

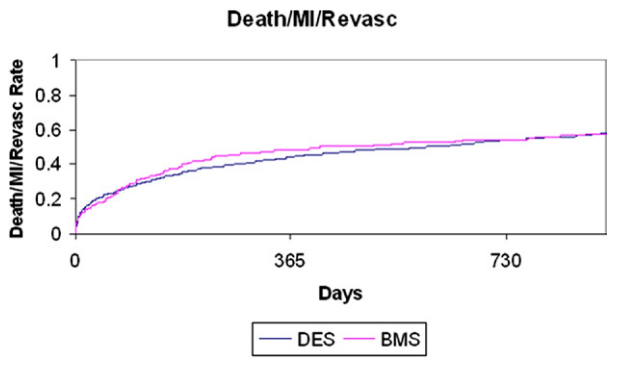

Figure 6 Adjusted Cumulative Incidence

Adjusted cumulative incidence of death, MI, or repeat Revasc, stratified by stent type. Abbreviations as in Figure 3.

possible in this setting, as no prior clinical trials have randomized ULMCA patients to DES versus BMS.

Implications for future research. These results emphasize the need for a well-powered randomized clinical trial examining the safety and effectiveness of percutaneous revascularization in patients with ULMCA disease, with attention to the generalizability of U.S. patients recruited for trial participation and best practices in procedural techniques for revascularization.

Conclusions

ULMCA PCI remains a relatively uncommon procedure at most U.S. centers and is primarily reserved for those at high risk for coronary artery bypass graft surgery. Poor outcomes following percutaneous revascularization in elderly ULMCA patients are common and are likely influenced by both patient and procedural characteristics.

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Key Words: long-term outcomes ■ percutaneous revascularization ■ unprotected left main coronary artery stenosis.

APPENDIX

For supplemental tables, please see the online version of this paper.